Remarks

Double Patenting:

Claims 1-3 and 9 have been rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1, 2, 6, and 7 of U.S. Patent 5,744,335 in view of Boussif et al. (WO 01/59087) and Fire et al. (U.S. Patent No. 6,506,559).

The Action states on Page 4 that the '335 patent teaches the amphipathic compound but does not teach polyvinylamine. Boussif et al. teach the use of polyvinylamine to deliver an antisense DNA. The Action concludes that based on these teachings, one of skill in the art would have known that polyvinylamine is suitable to deliver antisense oligonucleotides to cells. Finally stating that the '335 patent claims taken with Boussif et al. and Fire et al., which teaches siRNA, that it would have been obvious to one of skill in the art, at the time the invention was made, to modify the patent claims. Concluding that the '335 claims are variants of the present application claims.

The §1.132 Declaration submitted by Applicants in response to the prior Office Action also applies to this Office Action. The Declaration states that the cationic polymer, histone, plus the amphipathic compound and plasmid DNA from the cited '335 patent form an effective plasmid DNA delivery agent. However the cationic polymer from Boussif et al., polyvinylamine, plus the amphipathic compound and plasmid DNA does not form an effective plasmid DNA delivery agent. The data is provided.

Therefore, it could not have been obvious, at the time the invention was made, to substitute polyvinylamine for histone. In fact, the data shows that one having skill in the art would have been taught away from the substitution suggested in the Action. The only prior art at the time of the invention was delivery of large strands of DNA and delivery components for assisting transfection of very short siRNA was unknown. "A prima facie case of obviousness can be rebutted if the applicant...can show that the art in any material respect 'taught away' from the claimed invention." In re Haruna, 249 F.3d 1327, 58USPQ2d 1517 (Fed. Cir. 2001).

A person having skill in the art who considered the '335 patent in view of Boussif et al. and Fire et al. would not have gone through the exhaustive listing of every known polycation in

Boussif et al., where polyvinylamine was not even used in the working examples, and substituted it for histone since, at the time, the prevailing knowledge was that polyvinylamine would not perform delivery.

Rejection of claims under 35 U.S.C. 103:

Claims 1-3, 5 and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Boussif et al. (WO 01/5907) in view of Wolff et al. (U.S. Patent No. 5,744,335), Bischoff et al. (U.S. Patent No. 6,291,423) and Fire et al. (U.S. Patent No. 6,505,559).

The Action states in the last paragraph on page 5 that Boussif et al. teach a method for transfecting a cell by using a composition comprising an amphipathic compound, polyvinylamine and a nucleic acid. However, Boussif et al. simply listed the name of the compound, polyvinylamine, along with numerous other polycations, and did not show it in their working examples. That is because, as shown in Applicants' Declaration, polyvinylamine does not deliver the plasmid DNA that Boussif was attempting to deliver. This fact was known at the time of filing Applicants' claims as can be shown by the Examiner's reference to the '335 patent on page 6 of the Action.

The inventors of the '335 patent, Wolf et al., are also inventors in this application. They have supplied the §1.132 Declaration using data known at the time of filing for the delivery of plasmid DNA. Plasmid DNA was the DNA delivered in the referenced prior art and the significant differences between the delivery properties of plasmid DNA and siRNA were unknown at the time of filing this application. However, it was known by the inventors that the polyvinylamine did not perform delivery of the plasmid DNA described in Wolf et al. and Boussif et al.

A rejection under 35 U.S.C. 103(a) would be appropriate if a person of ordinary skill would have been motivated to modify a primary reference by deleting features thereof or by interchanging with or adding features from pertinent secondary references. However, the prohibition against destroying the function of the combination is inherent in the logic behind combining references to render a claimed invention obvious. If the proposed combination of the references so alters the primary reference that its broad function can no longer be carried

out, the combination of the prior art would not have been obvious to a designer of ordinary skill in the art.

Applicants have shown, in the Declaration under 37 C.F.R. 1.132, that polyvinylamine/1,4-disubstituted piperazine/DNA complexes are not effective plasmid DNA transfection complexes. Conversely, histone/1,4-disubstituted piperazine/siRNA complexes are not effective siRNA transfection complexes. Therefore, histone and polyvinylamine have patentably distinct properties. Furthermore, while '335 teaches that histone/1,4-disubstituted piperazine may be an effective plasmid DNA transfection composition, the data in the declaration clearly show that histone/1,4-disubstituted piperazine is not an effective (siRNA) transfection reagent. Therefore, the finding that polyvinylamine/1,4-disubstituted piperazine does form an effective siRNA transfection composition must be considered to be an unexpected result.

In view of the arguments presented above, Applicants respectfully request reconsideration of the rejections.

The Examiner's rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-3, 5 and 9 should be allowable.

Respectfully submitted,

/Mark K Johnson/
Mark K Johnson, Reg. No. 35,909
Mirus Bio Corporation
545 Science Dr., Suite A
Madison, WI 53711
608-441-2849

I hereby certify that this correspondence is being transmitted to the USPTO on this date: 1/23/2010 .

/Mark K Johnson/
Mark K Johnson